

Mitretek Report on Supplemental Testing of Lot FAV 031 of Anthrax Vaccine Absorbed

1. Lot Identity

Lot number FAV 031

2. Testing Dates

Supplemental testing was performed at BioPort Corporation (formerly Michigan Biologic Products Institute [MBPI]) beginning on 4 January 1998 and concluding on 30 October 1998. Samples were collected on 4 January 1998, and specific testing dates are listed under each test below. Results were reported by BioPort on 8 October 1999.

3. Standard Operating Procedures (SOPs)

All tests were performed using the most recent version of the applicable BioPort/ MBPI SOPs. Some SOPs were updated after the test plan was written but before the testing began. Changes in the SOPs were technically acceptable, and had no detrimental effect on testing.

4. Testing Summary

The vaccine lot passed all supplemental testing. All testing was performed according to Food and Drug Administration (FDA) guidelines and BioPort SOPs. All results were acceptable, and all associated quality control samples were acceptable. The report issued by BioPort is an accurate reflection of the testing.

Minor deviations from the SOPs occurred during testing. These deviations are noted below, but had no impact on the results.

All steps of the sampling and testing were observed by Mitretek personnel.